

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61B 17/36</b>	<b>A1</b>	(11) International Publication Number: <b>WO 97/17904</b> (43) International Publication Date: 22 May 1997 (22.05.97)
--	-----------	--

(21) International Application Number: PCT/US96/18101

(22) International Filing Date: 8 November 1996 (08.11.96)

(30) Priority Data:  
08/558,131 13 November 1995 (13.11.95) US

(71) Applicant: EP TECHNOLOGIES, INC. [US/US]; 350 Potrero Avenue, Sunnyvale, CA 94086 (US).

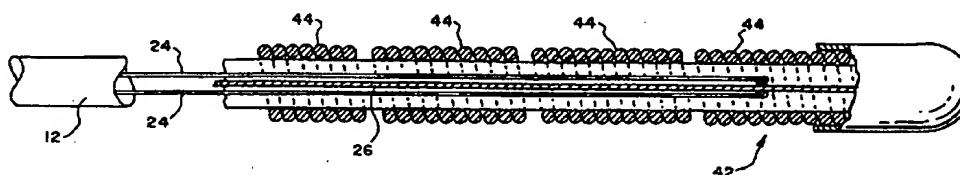
(72) Inventors: FLEISCHMAN, Sidney, D.; 855 Woodland Avenue, Menlo Park, CA 94025 (US). THOMPSON, Russell, B.; 123 West Portola Avenue, Los Altos, CA 94022 (US). PANESCU, Dorin; 382 North Fair Oaks, No. 4, Sunnyvale, CA 94086 (US). SWANSON, David, K.; 877 Heatherstone Way, Mountain View, CA 94040 (US).

(74) Agents: RYAN, Daniel, D. et al.; 633 West Wisconsin Avenue, Milwaukee, WI 53203 (US).

(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published  
With international search report.

(54) Title: FLEXIBLE TISSUE ABLATION ELEMENTS FOR MAKING LONG LESIONS



(57) Abstract

This invention is devices and methods for ablating body tissue which use wire (44) wound about a support body (12) in adjacent windings to form one or more elongated electrodes. A connection couples the wire to a source of ablation energy for transmission by the elongated electrode to ablate tissue. The adjacent windings are spaced apart to impart enhanced flexibility to the elongated electrode during use.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LJ	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

- 1 -

**FLEXIBLE TISSUE ABLATION ELEMENTS FOR  
MAKING LONG LESIONS**

**Related Cases**

5        This case is a continuation-in-part of U.S.  
Application Serial No. 08/287,192, filed August 8,  
1994, entitled "Systems and Methods for Forming  
Elongated Lesion Patterns in Body Tissue Using  
Straight or Curvilinear Electrode Elements." This  
case is also a continuation-in-part of U.S.  
10      Application Serial No. 08/439,824, filed May 12,  
1995, entitled "Systems and Methods for Controlling  
Tissue Ablation Using Multiple Temperature Sensing  
Elements."

**Field of the Invention**

15        The invention relates to systems and  
methods for ablating myocardial tissue for the  
treatment of cardiac conditions.

**Background of the Invention**

20        Physicians make use of catheters today in  
medical procedures to gain access into interior  
regions of the body to ablate targeted tissue areas.  
It is important for the physician to be able to  
precisely locate the catheter and control its  
emission of energy within the body during tissue  
25      ablation procedures.

For example, in electrophysiological  
therapy, ablation is used to treat cardiac rhythm  
disturbances.

30        During these procedures, a physician steers  
a catheter through a main vein or artery into the

- 2 -

interior region of the heart that is to be treated. The physician places an ablating element carried on the catheter near the cardiac tissue that is to be ablated. The physician directs energy from the  
5     ablating element to ablate the tissue and form a lesion.

          In electrophysiological therapy, there is a growing need for ablating elements capable of providing lesions in heart tissue having different  
10     geometries.

          For example, it is believed the treatment of atrial fibrillation requires the formation of long lesions of different curvilinear shapes in heart tissue. Such long lesion patterns require the  
15     deployment within the heart of flexible ablating elements having multiple ablating regions. The formation of these lesions by ablation can provide the same therapeutic benefits the complex suture patterns that the surgical maze procedure presently  
20     provides, but without invasive, open heart surgery.

          As another example, it is believed that treatment of atrial flutter and ventricular tachycardia requires the formation of relatively large and deep lesion patterns in heart tissue. Merely providing "bigger" electrodes does not meet  
25     this need. Catheters carrying large electrodes are difficult to introduce into the heart and difficult to deploy in intimate contact with heart tissue. However, by distributing the larger ablating mass required for these electrodes among separate,  
30     multiple electrodes spaced apart along a flexible body, these difficulties can be overcome.

          With larger and/or longer multiple electrode elements comes the demand for more precise  
35     control of the ablating process. The delivery of

- 3 -

ablating energy must be governed to avoid incidences of unwanted tissue damage and coagulum formation. The delivery of ablating energy must also be carefully controlled to assure the formation of uniform and continuous lesions, without hot spots and/or gaps forming in the ablated tissue.

Summary of the Invention

The invention provides devices and methods for ablating body tissue. The devices and methods wind wire about a support body in adjacent windings to form one or more elongated electrodes. A connection couples the wire to a source of ablation energy for transmission by the elongated electrode to ablate tissue. According to the invention, the adjacent windings are spaced apart to impart enhanced flexibility to the elongated electrode.

In a preferred embodiment, the adjacent windings are spaced apart by at least  $1/5$ th of the width of the wire. In a preferred implementation, the windings are spaced apart by about  $1/2$  the width of the wire.

In a preferred embodiment, the elongated electrode has at least one edge adjoining the support body. In this embodiment, the adjacent windings are spaced farther apart away from the edge than at the edge. In one implementation, spacing between adjacent windings varies away from the edge. In another implementation, spacing between adjacent windings is generally uniform away from the edge.

In a preferred embodiment, a temperature sensing element is carried by the electrode near the at least one edge, where the adjacent windings are closer together to support it.

In a preferred embodiment, the connection couples the wire to a source of radio frequency

- 4 -

ablation energy for transmission by the elongated electrode to ablate tissue.

Other features and advantages of the inventions are set forth in the following Description and Drawings, as well as in the appended Claims.

**Brief Description of the Drawings**

Fig. 1 is a view of a probe that carries a flexible ablating element comprising an array of spaced apart coil electrodes;

Fig. 2 is an enlarged view of the array of spaced apart coil electrodes carried by the probe shown in Fig. 1;

Fig. 3 is an enlarged view of the handle of the probe shown in Fig. 1, with portions broken away and in section, showing the steering mechanism for flexing the ablating element;

Fig. 4 is an enlarged side section view of the ablating element further showing the steering mechanism for flexing the ablating element;

Figs. 5 and 6 are, respectively, side and side section views of tightly wrapped round and flat wire comprising coil electrodes;

Figs. 7 and 8 are, respectively, side and side section views of spaced apart windings of round and flat wire comprising coil electrodes;

Fig. 9 is a diagrammatic view of a flexible coil electrode element showing two dimensions that help characterize the flexibility of the electrode element in terms of its shape;

Fig. 10 is a diagrammatic view of a flexible coil electrode element showing dimensions that help characterize the flexibility of the electrode element in terms of its ability to form tight curves of small radii;

- 5 -

Fig. 11 is a diagrammatic view of a flexible coil electrode element showing dimensions that help characterize the flexibility of the electrode element in terms of its ability to achieve uniform intimate contact against heart tissue;

Fig. 12 is a side view of a multiple zone flexible coil electrode, which provides enhanced flexibility as well accommodates placement of temperature sensing elements;

Fig. 13 is a side view of an alternative embodiment of a multiple zone flexible coil electrode;

Fig. 14 is a side view of an ablation element carrying individual coil electrodes that are not sufficiently flexible to conform to the desired curve of the element, causing gaps in tissue contact;

Fig. 15 is a side view of an ablation element carrying individual coil electrodes that are sufficiently flexible to conform to the desired curve of the element, creating uniform tissue contact along the length of the element;

Fig. 16 is a perspective section view of an alternative embodiment of a flexible ablation element carrying spaced apart coil electrodes in sidelong channels;

Fig. 17 is a side section view of the ablation element shown in Fig. 16, the ablation element being shown in an unflexed condition; and

Fig. 18 is a side section view of the ablation element shown in Fig. 16, the ablation element being shown in a flexed condition;

The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is

- 6 -

defined in the appended claims, rather than in the specific description preceding them. All embodiments that fall within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

#### Description of the Preferred Embodiments

This specification discloses multiple electrode structures that embody aspects of the invention. This specification also discloses tissue ablation systems and techniques using multiple temperature sensing elements that embody other aspects of the invention. The illustrated and preferred embodiments discuss these structures, systems, and techniques in the context of catheter-based cardiac ablation. That is because these structures, systems, and techniques are well suited for use in the field of cardiac ablation.

Still, it should be appreciated that the invention is applicable for use in other tissue ablation applications. For example, the various aspects of the invention have application in procedures for ablating tissue in the prostate, brain, gall bladder, uterus, and other regions of the body, using systems that are not necessarily catheter-based.

#### I. Flexible Ablating Elements

Figs. 1 and 2 show a flexible ablating element 10 for making lesions within the heart.

The element 10 is carried at the distal end of a catheter body 12 of a probe 14. The probe 14 includes a handle 16 at the proximal end of the catheter body 12. The handle 16 and catheter body 12 carry a steering mechanism 18 for selectively bending or flexing the ablating element 10 in two opposite directions, as Figs. 1 and 2 show.

- 7 -

The steering mechanism 18 can vary. In the illustrated embodiment (see Figs. 3 and 4), the steering mechanism 18 includes a rotating cam wheel 20 with an external steering lever 22 (also see Fig. 1) carried by the handle 16. As Fig. 3 shows, the cam wheel 20 holds the proximal ends of right and left steering wires 24. The wires 24 pass through the catheter body 12 and connect to the left and right sides of a resilient bendable wire or leaf spring 26 (see Fig. 4) supported at the distal end of the catheter body 12.

Further details of this and other types of steering mechanisms for the ablating element 10 are shown in Lundquist and Thompson U.S. Patent 5,254,088, which is incorporated into this Specification by reference.

As Fig. 1 shows, forward movement of the steering lever 22 flexes or curves the ablating element 10 in one direction. Rearward movement of the steering lever 22 flexes or curves the ablating element 10 in the opposite.

Various access techniques can be used to introduce the probe 14 into the desired region of the heart. For example, to enter the right atrium, the physician can direct the probe 14 through a conventional vascular introducer through the femoral vein. For entry into the left atrium, the physician can direct the probe 14 through a conventional vascular introducer retrograde through the aortic and mitral valves.

Alternatively, the physician can use the delivery system shown in pending U.S. Application Serial No. 08/033,641, filed March 16, 1993, and entitled "Systems and Methods Using Guide Sheaths for Introducing, Deploying, and Stabilizing Cardiac

- 8 -

Mapping and Ablation Probes."

5       The physician can verify intimate contact  
between the element 10 and heart tissue using  
conventional pacing and sensing techniques. Once the  
physician establishes intimate contact with tissue  
in the desired heart region, the physician applies  
ablating energy to the element 10. The type of  
ablating energy delivered to the element 10 can  
vary. In the illustrated and preferred embodiment,  
10   the element 10 transmits electromagnetic ablating  
energy with a frequency below about 1.0 GHz. This  
type of ablating energy, which is referred to as  
radio frequency energy, heats tissue, mostly  
ohmically, without electrically stimulating it.  
15   Alternatively, the element can transmit  
electromagnetic ablating energy with a frequency  
above 1.0 GHz. This type of ablating energy, which  
is referred to as microwave energy, produces both  
ohmic and dielectric tissue heating effects.

20       The ablating element 10 can be conditioned  
to form elongated lesion patterns. These elongated  
lesion patterns can be continuous and extend along  
a straight line or along a curve. Elongated lesion  
patterns can be used to treat, for example, atrial  
25   fibrillation.

Fig. 2 shows one embodiment of the flexible  
ablating element 10. In this embodiment, a flexible  
body 42 carries on its exterior surface an array of  
spaced apart, generally flexible electrodes 44. In  
30   this embodiment, each electrode 44 comprises wire  
wound in relatively tight spiral coils.

The flexible body 42 is made of a  
polymeric, electrically nonconductive material, like  
polyethylene or polyurethane. It is the body 42 that  
35   carries within it the resilient bendable wire or

- 9 -

leaf spring 26 with attached steering wires 24, as Fig. 4 shows, for flexing the body 42 and, with it, the array of electrodes 44.

5 The coil electrodes 44 are made of electrically conducting wire material. Copper alloy, platinum, or stainless steel 304, 0303, 17-7 can be used. Drawn, filled tubing comprising a stainless steel outer tubing with a platinum or silver inner core can also be used. The electrically  
10 conducting wire material of the coil electrodes 44 can be coated with platinum-iridium or gold to improve its conduction properties and biocompatibility.

The coil electrodes 44 can be made of  
15 closely wound, generally cylindrical wire, as the coil 44(a) shown in Figs. 5 and 6. Preferably, the coil electrodes 44 are made of wound wire having a flat, or rectangular, cross section, as the coil 44(b) shown in Figs. 5 and 6. Wire having a flat  
20 cross section is preferred for several reasons.

First, using wire having a flat cross section, the tissue contact surface area of the resulting coil electrode 44(b) can be increased in an axial direction (i.e., along the body 42) without  
25 increasing the outside diameter of the electrode 44(b). More compact and easily deployable ablating elements 10 result.

Moreover, a wire having a flat cross section, when wound into a coil electrode 44(b),  
30 permits a more efficient transmission of radio frequency ablation energy. Efficient transmission of radio frequency ablation energy by a coil electrode 44 requires keeping DC resistances between the point of electrical contact with the signal wire  
35 and any location on the coil at or below about 10

- 10 -

ohms. As resistances exceed about 10 ohms, the radio frequency current densities transmitted by the coil electrode 44 decrease substantially with the distance from the electrical connection. Using wire having a flat cross section, it is possible to maintain the outside and inside diameters of the wound coil electrode 44(b), and still control resistances, solely by changing the width of the wire. Furthermore, as the width of the wire increases, so can the spacing between windings, decreasing the length of wire.

The overall flexibility of the element 10 is important to consistently achieve intimate contact with heart tissue along the length of the element 10 and heart tissue. Without intimate contact along the entire length of the element 10, transmission of radio frequency energy lacks uniformity, thus resulting in undesired gaps in lesion patterns. Gaps in the lesion pattern are known to be proarrhythmic and can lead to atrial flutter.

The dynamic, nonlinear nature of the endocardium complicates the matter. To consistently create intimate tissue contact, the ablation element 10 must have the capability to flexibly adapt to a wide range of contours and interior spaces within the heart.

It has been discovered that closely wound coil electrodes 44(a) and 44(b) shown in Fig. 5 and 6, do not always provide intimate tissue contact along the length of the element 10. Arrays of closely wound coil electrodes 44(a) and 44(b) often lack the flexibility to be easily bent into tight curves, having small curve radii. The individual coil electrodes 44(a) and 44(b) along the length of

- 11 -

the element 10 often do not bend uniformly. Some coil electrodes 44(a) and 44(b) within the array retain straight, tangential profiles, particularly in the regions where the bend in the desired curve is most acute. Steering difficulties and gaps in lesion patterns may result.

It has been discovered that the flexibility and performance of elements 10 comprising arrays of wound coil electrodes 44 can be significantly enhanced by spacing the wire windings in a prescribed way. Figs. 7 and 8 show a preferred embodiment of the ablating element 10 incorporating this discovery.

In this embodiment, the same flexible body 42 carries on its exterior surface an array of spaced apart lengths of wound, helical coils forming electrodes, designated 44(c) and 44(d) in Figs. 7 and 8. Unlike the closely spaced wire windings shown in Figs. 5 and 6, in Figs. 7 and 8, the wire windings in each coil electrode 44(c) and 44(d) have been spread apart by a distance D. This results from increasing the pitch of the individual wire windings forming the coil electrodes 44(c) and 44(d).

The spread-apart coil electrodes can be made of generally cylindrical wire, as the coil electrode 44(c) shown in Figs. 7 and 8. Still, however, it is preferred that the wire forming the spread-apart coil electrodes have a flat, or rectangular, cross section, as the coil electrode 44(d) shown in Figs. 7 and 8. The same reasons set forth above for preferring a flat cross section apply.

The enhanced physical characteristics of the spread apart coil electrodes 44(c) and 44(d) in

- 12 -

Figs. 7 and 8, when compared to the adjacent coil electrodes 44(a) and 44(b) in Figs. 5 and 6, can be demonstrated with respect to three physical functions. These functions differentiate flexibility among ablating elements 10 comprising arrays of spaced apart coil electrodes 44 in terms of flexed shape, degree of flexed curvature, and degree of tissue contact when flexed.

The first function ( $F_s$ ) (see Fig. 9) relates to the shape of a flexible coil ablating element 10, when flexed. When flexed, the dimensions of the curvilinear ablating element 10 can be expressed in terms of a perpendicular distance to the first bend ( $D_p$ ) and a maximum diameter ( $D_M$ ). The function  $F_s$  can be expressed as a ratio of these two dimensions, as follows:

$$F_s = \frac{D_p}{D_M}$$

The closer  $F_s$  is to 1, the more iso-radial, or circular, the flexed structure 10 is. When  $F_s \approx 1$ , the flexed structure 10 becomes circular. When  $F_s < 1$ , the main axis of the ellipse is generally parallel to the axis of the catheter body 12, as Fig. 9 shows. When  $F_s > 1$ , the main axis of the ellipse is generally perpendicular to the axis of the catheter body 12.

The second function ( $F_r$ ) (see Fig. 10) relates to the degree of curvature defined by the ablating element 10, when flexed. As Fig. 10 shows, when the element 10 is flexed, the individual coil electrode  $C(i)$  ( $i = 1$  to  $N$ , where  $N$  is the number of electrodes) will each assume its own radius of curvature ( $R_{C(i)}$ ).  $F_r$  can be expressed in terms of an

- 13 -

average of the radii of curvature of the individual coil elements, as follows:

$$F_T = \frac{\sum_{i=1}^{i=N} R_{C(i)}}{N}$$

The magnitude of  $F_T$  points to how acutely the element 10 can be flexed. As  $F_T$  decreases, the smaller the overall radius of curvature for the entire flexed element 10 is, and the more the element 10 is able to be flexed into a tight curve.

The third function  $F_C$  (see Fig. 11) relates to the uniformity of contact between tissue along the length of the flexed element 10. When flexed, tangents can be drawn at the edges of adjacent coil electrodes  $C(i)$  and  $C(i+1)$ , designated  $T(i)$  and  $T(i')$  in Fig. 11. The tangents  $T(i)$  and  $T(i')$  intersect for each electrode  $C(i)$  to form angles  $A_{T(i,i')}$ .  $F_C$  can be expressed as the average of the tangent angles along the length of the element, as follows:

$$F_C = \frac{\sum_{i=1}^{i=N-1} A_{T(i,i')}}{N-1}$$

Individual coil electrodes 44 that are not sufficiently flexible to conform to the desired curve of the element 10 will form straight sections along the length of the flexed element 10, as Fig. 14 shows. Tissue contact between successive straight sections will not be uniform. Gaps in contact (designated G in Fig. 14) can occur, creating gaps in lesions and undesired proarrhythmic effects.

The presence of straight sections will increase the magnitude of the tangent angles  $A_{T(i,i')}$ .

- 14 -

As  $F_c$  increases, the likelihood of non-uniform tissue contact along the flexed structure increases, as does the likelihood of gaps between lesions. Conversely, as  $F_c$  decreases, the likelihood that the flexed element 10 will conform uniformly along its length to the curvilinear contour of tissue, without straight sections and gaps (as Fig. 15 shows), increases.

#### EXAMPLE

Four flexible ablation elements 10 were built for comparison, designated elements E1, E2, E3, and E4. Each ablation element E1-4 comprised six coil electrodes, each coil electrode being 12.5 mm in length. The coil electrodes were spaced apart by 2 mm. Each ablation element E1-4 used the same steering mechanism, as generally shown in Figs. 3 and 4 and as earlier described.

The coil electrodes in ablation elements E1 and E2 used round wire having an outside diameter of 0.012 inch. In E1, the windings were adjacent, as represented by coil electrode 44(a) in Fig. 5. In E2, the windings were spaced apart, as represented by electrode 44(c) in Fig. 7. In E2, the distance D that the coil electrodes were spaced apart was  $\frac{1}{2}$  the width of the wire, designated by the letter W in Fig. 7 (i.e.,  $D = \frac{1}{2}W$ ).

Ablation elements E3 and E4 used flat wire, 0.020 inch wide and 0.005 inch high. In E3, the windings were adjacent, as represented by electrode 44(b) in Fig. 5. In E4, the windings were spaced apart, as represented by electrode 44(d) in Fig. 7. In E4, the distance D that the coil electrodes were spaced apart was  $\frac{1}{2}$  the width of the wire, also designated by the letter W in Fig. 7 (i.e.,  $D = \frac{1}{2}W$ ).

The physical characteristics  $F_s$ ;  $F_l$ ; and  $F_c$

- 15 -

of the ablation elements E1, E2, E3, and E4 were tested. The following Tables summarize the test results:

TABLE 1:  $F_s$ 

5		$D_p$ (inch)	$D_M$ (inch)	$F_s$
	E1 Round/Tight	1.05	1.18	1.12
	E2 Round/Spread	0.86	0.95	1.11
10	E3 Flat/Tight	0.92	1.11	1.21
	E4 Flat/Spread	0.69	0.77	1.12
15				

TABLE 2:  $F_T$ 

		$F_T$
	E1 Round/Tight	$1.23 \pm 0.49$
20	E2 Round/Spread	$0.55 \pm 0.24$
	E3 Flat/Tight	$0.79 \pm 0.38$
25	E4 Flat/Spread	$0.52 \pm 0.26$

- 16 -

TABLE 3:  $F_c$ 

	$F_c$
E1 Round/Tight	$35^0 \pm 8$
E2 Round/Spread	$26^0 \pm 8$
E3 Flat/Tight	$31^0 \pm 11$
E4 Flat/Spread	$14^0 \pm 6$

DC resistance (in ohms) was also measured for each ablation element, as set forth in the following Table:

TABLE 4: Coil Resistance

	DC Resistance (Ohms)
E1 Round/Tight	$3.32 \pm 0.62$
E2 Round/Spread	$2.68 \pm 0.70$
E3 Flat/Tight	$2.17 \pm 0.16$
E4 Flat/Spread	$1.67 \pm 0.12$

The amount of force required to fully bend each ablation element E1; E2; E3; and E4 was measured ( $F_{BEND}$ ), as was the force to straighten out a each bent element ( $F_{UNBEND}$ ), as set forth in the following table:

- 17 -

TABLE 5: BENDING FORCES

	$F_{\text{BEND}}$ (lbf-in)	$F_{\text{UNBEND}}$ (lbf-in)
E1 Round/Tight	$2.90 \pm 0.06$	$2.90 \pm 0.10$
E2 Round/Spread	$2.53 \pm 0.15$	$2.53 \pm 0.12$
E3 Flat/Tight	$3.23 \pm 0.06$	$3.23 \pm 0.12$
E4 Flat/Spread	$2.87 \pm 0.15$	$2.87 \pm 0.12$

The foregoing example shows:

(1) When the windings of the coil elements are brought farther apart (both round and flat wires)(Table 1), the absolute value of  $F_s$  decreases, getting closer to 1.

(2) For both round and flat wires, the values of  $F_r$  and  $F_c$  decrease when the windings of the coil elements are spaced further apart (Tables 2 and 3).

Thus, regardless of flat or round coil configurations, spaced apart windings create an overall more flexible ablation element, which can more readily be bent into shapes having smaller radii of curvature and with greater likelihood of creating continuous zones of intimate contact with tissue, like that shown in Fig. 15. Moreover, in tightly wound coil configurations, adjacent windings can overlap during bending, which could potentially "pinch" the endocardium.

The foregoing Example also shows that the spread apart flat wire configuration (E4) achieves the lowest  $F_c$  (Table 3), and thus presents the

- 18 -

highest likelihood of a conformal curve against tissue. The force to achieve a curve using the spread flat wire configuration E4 is greater than a spread round wire (E2) (Table 5); but the curve for the spread flat wire configuration (E4) is "tighter" and thus better than for the spread round wire configuration (E2) (Table 2).

The foregoing Example demonstrates the mechanical benefits of separating the windings in the coils.

It has been determined that the benefits of greater flexibility arose when the distance D between the windings is at least 1/5th the width W of the wound wire. It has been determined that spacing of less than 1/5th the width W of the wound wire leads to significantly less flexibility, with greater potential for pinching tissue between the windings. The most preferred distance D is believed to be about  $\frac{1}{2}$  the width W of the wound wire.

How far apart the windings should be spread to achieve the benefits of greater flexibility depends largely upon the desired heating effect. If additive heating effects between adjacent windings are desired to form continuous lesions between the windings, the upper spacing limit becomes the distance at which the desired additive heating effect is observed to diminish. The diminishing of the additive heating effect can be determined empirically or mathematically under the desired operating conditions and geometries.

Various ways to control the characteristics of lesions formed by the ablating elements 10 are disclosed in detail in U.S. Application Serial No. 08/287,192, filed August 8, 1994, entitled "Systems and Methods for Forming Elongated Lesion Patterns in

- 19 -

Body Tissue Using Straight or Curvilinear Electrode Elements" and in U.S. Application Serial No. 08/439,824, filed May 12, 1995, entitled "Systems and Methods for Controlling Tissue Ablation Using Multiple Temperature Sensing Elements", which are  
5 incorporated herein by reference.

Above-identified U.S. Application Serial No. 08/439,824 shows the use of temperature sensing elements to measure temperatures along the length of the ablation element 10. As disclosed in this prior  
10 application, the positioning of the temperature sensing elements on the electrode elements 10 is important for achieving reliable temperature sensing, particularly when the length of an individual coil on the element 10 exceeds about 10  
15 mm, as contemplated in the preferred embodiment of this application.

Fig. 12 shows a preferred embodiment of a coil electrode 50 designed for enhanced flexibility as well as to accommodate optimal placement of temperature sensing elements 52. As Fig. 12 shows,  
20 the coil electrode 50 comprises two zones 54 and 56.

The first zone 54 represents the majority of the electrode 50, occupying its entire mid portion. The first zone 54 comprises spaced apart windings to provide enhanced flexibility, as already  
25 described.

The second zone 56 occupies each edge of the coil electrode 50. The second zone 56 comprises a region where the windings are closely adjacent to each other. The closeness of the windings provides a support structure for the temperature sensing  
30 element 52.

As Fig. 12 shows, the temperature sensing elements 52 are threaded up through the windings in  
35

- 20 -

each second zone 56 to lay upon its exterior surface. In the illustrated embodiment, the sensing elements 52 comprise thermocouples, and each is encapsulated in an epoxy or PTFE coating 58.

5 However, thermistors can be used.

Preferably, as shown in phantom lines in Fig. 12, the temperature sensing elements 52 can be secured to the inside surface of each second zone 56. Still alternatively, the sensing elements 52  
10 can be sandwiched between the inside surface of the second zones 56 and the underlying flexible body 42.

The two zone structure of the coil electrode 50 shown in Fig. 12 allows placement of temperature sensing elements 52 at the side edges 60  
15 of the electrode 50. These edges 60 are where the electrode 50 abuts the underlying, non-electrically-conductive support body 42. RF current densities are high at these edges 60, because the edges 60 are regions where electrical conductivity is  
20 discontinuous. The resulting rise in current density at the electrode edges 60 generates localized regions of increased power density and, therefore, regions where higher temperatures exist. Given the elongated size of the electrode 50,  
25 temperature sensing elements 52 should preferably be located in these edge regions where high localized temperatures are to be expected. The closely spaced windings at the second region 56 accommodate such placement, without detracting from the overall  
30 flexibility that the first region 54 provides.

In a preferred embodiment (as Fig. 12 shows), a thin strip 66 of electrically insulating material (for example, an electrically nonconducting adhesive) is applied about the body 42 immediately  
35 next to the second regions 56. It has been observed

- 21 -

that the presence of this electrically nonconducting strip 56 helps to minimize the presence of edge-effect currents, which tend to be more pronounced in coil electrodes than other electrode structures.

5           Fig. 13 shows an alternative embodiment of a coil electrode 60 designed for enhanced flexibility as well as to accommodate optimal placement of temperature sensing elements 52. Fig. 13 is similar to Fig. 12, in that the coil electrode 10 60 comprises at least two zones 62 and 64 of different spacing D between coil windings. In Fig. 12, the spacing D in the interior zone 54 is generally uniform, maintaining a distance at least 1/5th the width of the wire. In Fig. 13, the 15 spacing D in the interior zone 62 is at least 1/5th the width of the wire, but the actual distance D varies along the interior zone 62. As Fig. 13 shows, the spacing D in the interior zone 62 decreases progressively from the mid point of the 20 coil 60 toward the edge zones 64, where the windings are closely spaced (i.e., less than 1/5th the width of the wire) to support temperature sensing elements 52. Alternatively, the spacing D can vary along the interior zone 62 in a random fashion, while still 25 observing the minimum spacing of 1/5th the width of the wire. Practically speaking, it is to be expected that the spacing D will not be perfectly uniform or perfectly progressive, but will vary along the interior zone 62, because of normal 30 tolerance deviations in the manufacturing process.

As Fig. 13 also shows, the interior zone 62 (or, in Fig. 12, zone 54) could also carry a temperature sensing element 52. The use of a third, more centrally located temperature sensing element 35 52 is preferred when temperature prediction

- 22 -

algorithms are used, as disclosed in the copending Application Serial No. 08/439,824, as previously identified.

5 Figs. 16 to 18 show an alternative embodiment of a spaced-apart coil electrode 70 that achieves the benefits of the invention. In this embodiment, a flexible catheter body 72 includes an opposed pair of side channels 74 along its length. Each side channel 72 carries a spiral wound wire  
10 coil 76. The windings of the coil are spaced apart, in accordance with the invention, by at least  $1/5$ th the width of the wire.

The catheter body 72 carries within a resilient bendable wire or leaf spring with attached  
15 steering wire, as shown in Fig. 4 (but which is not shown in Figs. 16 to 18). As described in preceding embodiments (and as Fig. 18 shows), pulling on the steering wires flexes the body 72 in opposite directions along the axes of the channels 72,  
20 thereby also bending the wound coils 76. The spaced apart nature of the coils 76 provides enhanced flexibility, in the manner already described.

Regarding the several embodiments of the invention already discussed, it should be noted  
25 that, in addition to the mechanical advantage of enhanced flexibility, there are also considerable electrical advantages that attend the use of a coil electrode with spaced apart windings. A coil electrode with windings spaced apart in accordance  
30 with the invention provides a more uniform thermal profile in tissue heated by coil. This is because the current flow through the spaced apart windings is more uniform than it otherwise would be. The result is less temperature differentials along the  
35 length of the coil and the elimination of "hot

- 23 -

spots."

5       The provision of spaced apart windings in  
a coil implemented in accordance with the invention  
also makes possible the reduction of edge current  
effects. By coupling the energy signal wire 78 (see  
Fig. 8) to the mid portion of a spaced apart coil  
44(d), higher resistance between the coil mid  
portion and the edge of the coil can be achieved.  
10       This, in turn, decreases current density at the  
edge, thereby decreasing edge current effects.  
Without a spaced apart coil, one would have to turn  
to other techniques to reduce edge current effects,  
such as changing the length of the coil, thinning  
the cross sectional area of the coil, or changing  
15       the material of the coil.

      The invention therefore makes possible the  
attainment of both mechanical and electrical  
advantages beneficial to tissue ablation.

20       Various features of the invention are set  
forth in the following claims.

- 24 -

**WE CLAIM:**

1. A device for ablating body tissue comprising  
a support body,  
wire wound about the support body in adjacent  
5 windings to form an elongated electrode having at  
least one edge adjoining the support body, the  
adjacent windings being spaced closer together near  
the at least one edge than along the rest of the  
elongated electrode, and  
10 a connection coupling the wire to a source of  
ablation energy for transmission by the elongated  
electrode to ablate tissue.
2. A device according to claim 1  
wherein the wire has a rectilinear cross  
section.
3. A device according to claim 1  
wherein the wire has a circular cross section.
4. A device according to claim 1  
wherein spacing between the adjacent windings  
away from the at least one edge varies.
5. A device according to claim 1  
wherein spacing between the adjacent windings  
away from the at least one edge is generally  
uniform.
6. A device according to claim 1  
and further including at least one temperature  
sensing element on the electrode.
7. A device according to claim 1  
and further including a temperature sensing  
element near the at least one edge of the electrode.
8. A device according to claim 1  
wherein the wire has a width, and  
wherein the adjacent windings are spaced apart  
by at least 1/5th of the width of the wire except

- 25 -

5 near the at least one edge, where the adjacent windings are spaced closer than 1/5th of the width of the wire.

9. A device according to claim 1

wherein the adjacent windings are spaced apart by about  $\frac{1}{2}$  the width of the wire except near the at least one edge, where the adjacent windings are spaced closer than 1/5th of the width of the wire.

10. A device according to claim 1

wherein the connection couples the wire to a source of radio frequency ablation energy for transmission by the elongated electrode to ablate tissue.

11. A device for ablating body tissue comprising

a flexible support body having an axis,

a wire carried by flexible support body, the wire having a width and being wound in adjacent windings to form an elongated electrode, the adjacent windings being spaced apart by a distance at least 1/5th the width of the wire,

an element in the support body for flexing the support body relative to the axis and, with it, the elongated electrode, and

a connection coupling the wire to a source of ablation energy for transmission by the elongated electrode to form a lesion pattern that follows the flexed elongated electrode.

12. A device according to claim 11

wherein the wire is wound about the flexible support body.

13. A device according to claim 11

wherein the flexible body includes a channel, and

wherein the wire is carried within the

- 26 -

5       channel.

14. A device according to claim 11  
wherein the wire has a rectilinear cross  
section.

15. A device according to claim 11  
wherein the wire has a circular cross section.

16. A device according to claim 11  
wherein the connection couples the wire to a  
source of radio frequency ablation energy for  
transmission by the elongated electrode to ablate  
5       tissue.

17. A device for ablating body tissue  
comprising

a flexible support body,  
wire wound about the flexible support body in  
5       adjacent, spaced apart windings to form an array of  
at least two mutually spaced apart elongated  
electrodes,

an element in the support body for flexing the  
support body relative to the axis and, with it, the  
10       array of elongated electrodes, and

a connection coupling the wire to a source of  
ablating energy for transmission by the array of  
elongated electrodes to form a continuous lesion  
pattern that follows the flexed elongated  
15       electrodes.

18. A device according to claim 17  
wherein each elongated electrode has opposite  
edges adjoining the support body, and

wherein the adjacent windings of each  
5       elongated electrode are spaced farther apart away  
from the opposite edges than at the opposite edges.

19. A device according to claim 18  
wherein the wire has a width, and  
wherein the adjacent windings of each

- 27 -

5 elongated electrode are spaced apart by at least 1/5th of the width of the wire except near the opposite edges, where the adjacent windings are spaced closer than 1/5th of the width of the wire.

20. A device according to claim 19  
wherein the wire has a width, and  
wherein the adjacent windings of each  
5 elongated electrode are spaced apart by about 1/2 the width of the wire except near the opposite edges, where the adjacent windings are spaced closer than 1/5th of the width of the wire.

21. A device according to claim 19  
wherein spacing varies between the adjacent windings away from the opposite edges.

22. A device according to claim 19  
wherein spacing is generally uniform between the adjacent windings away from the opposite edges.

23. A device according to claim 17  
wherein the wire has a rectilinear cross section.

24. A device according to claim 17  
wherein the wire has a circular cross section.

25. A device according to claim 17  
wherein the connection couples the wire to a source of radio frequency ablation energy for transmission by the elongated electrodes to ablate  
5 tissue.

26. A device for ablating body tissue comprising

a flexible support body,  
wire wound about the flexible support body in  
5 adjacent, spaced apart windings to form an array of at least two mutually spaced apart elongated electrodes, each elongated electrode having opposite edges adjoining the support body,

- 28 -

an element in the support body for flexing the  
10 support body relative to the axis and, with it, the  
array of elongated electrodes,

a connection coupling the wire to a source of  
ablating energy for transmission by the elongated  
electrode to form a continuous lesion pattern that  
15 follows the flexed elongated electrodes, and

at least one temperature sensing element on  
each elongated electrode near at least one  
respective edge of the elongated electrode.

27. A device according to claim 26

wherein there is at least one temperature  
sensing element on each elongated electrode near  
both respective opposite edges.

28. A device according to claim 27

and further including a temperature sensing  
element on each elongated electrode between the  
respective opposite edges.

29. A device according to claim 26

wherein the adjacent windings of each  
elongated electrode are spaced farther apart away  
from the respective opposite edges than at the  
5 respective opposite edges.

30. A device according to claim 29

wherein the wire has a width, and  
wherein the adjacent windings of each  
elongated electrode are spaced apart by at least  
5 1/5th of the width of the wire except near the  
respective opposite edges, where the adjacent  
windings are spaced closer than 1/5th of the width  
of the wire.

31. A device according to claim 29

wherein spacing varies between the adjacent  
windings away from the respective opposite edges.

32. A device according to claim 29

- 29 -

wherein spacing is generally uniform between the adjacent windings away from the respective opposite edges.

33. A device according to claim 26 wherein the wire has a rectilinear cross section.

34. A device according to claim 26 wherein the wire has a circular cross section.

35. A device according to claim 26 wherein the connection couples the wire to a source of radio frequency ablation energy for transmission by the elongated electrodes to ablate tissue.

36. A device for ablating body tissue comprising  
a flexible support body having an axis,  
a wire carried by flexible support body, the wire having a width and being wound in adjacent windings to form an elongated electrode, the adjacent windings being spaced apart by a distance at least 1/5th the width of the wire, the elongated electrode having opposite edges adjoining the flexible support body and a mid region between the opposite edges, and

a signal wire coupled to the mid region of the elongated electrode to couple the elongated electrode to a source of ablation energy for transmission by the elongated electrode to ablate tissue.

37. A device according to claim 36 and further including an electrically non conducting material applied to the opposite edges and the flexible support body adjoining the opposite edges.

38. A method for ablating body tissue

- 30 -

comprising the steps of

5       deploying in the body a wire carried by a  
flexible support, the wire having a width and being  
wound in adjacent windings to form an elongated  
electrode, the adjacent windings being spaced apart  
by a distance at least  $1/5$ th the width of the wire,

flexing the support relative to the axis and,  
with it, the elongated electrode, and

10       coupling the wire to a source of ablation  
energy for transmission by the elongated electrode  
to form a lesion pattern that follows the flexed  
elongated electrode.

39. A method for ablating body tissue  
comprising the steps of

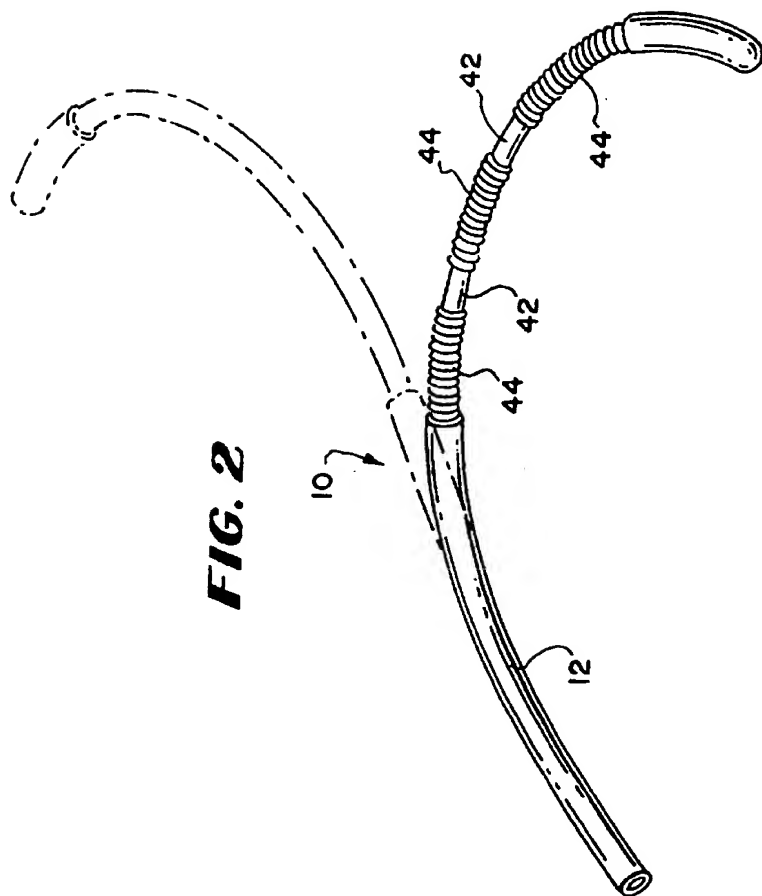
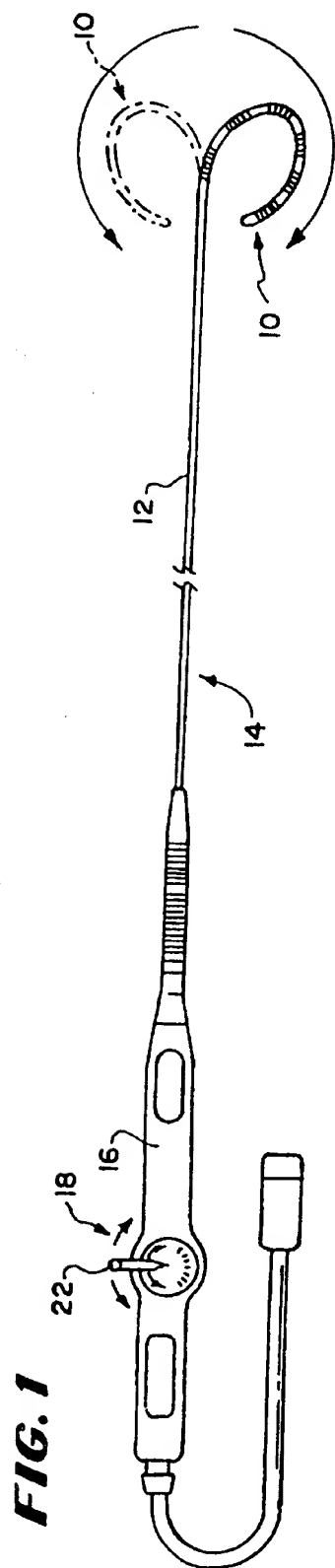
5       deploying in the body wire wound about a  
flexible support in adjacent, spaced apart windings  
to form an array of at least two mutually spaced  
apart elongated electrodes,

flexing the support relative to the axis and,  
with it, the array of elongated electrodes, and

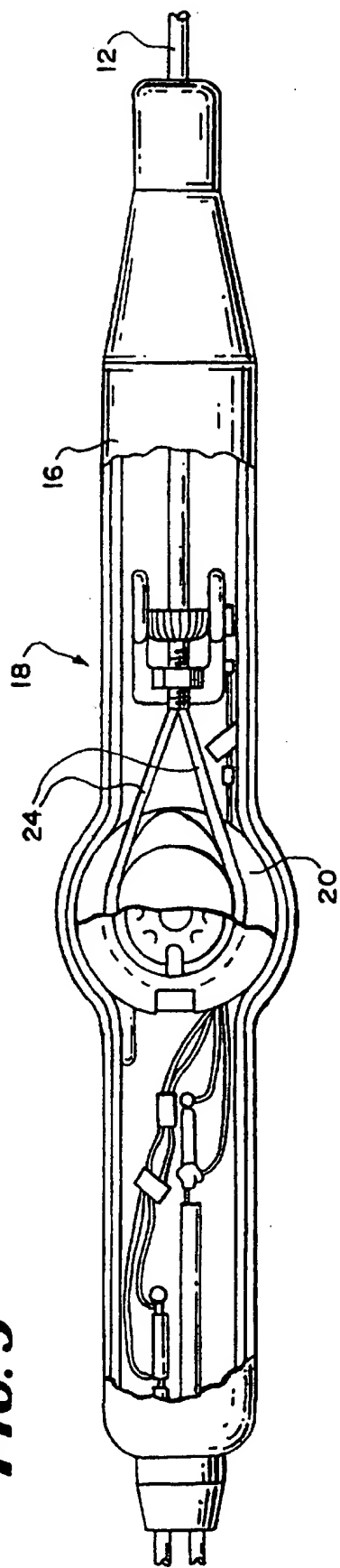
10       coupling the wire to a source of ablating  
energy for transmission by the array of elongated  
electrodes to form a continuous lesion pattern that  
follows the flexed elongated electrodes.

40. A method according to claim 38 or 39

wherein the coupling step includes coupling  
the wire to a source of radio frequency ablating  
energy.

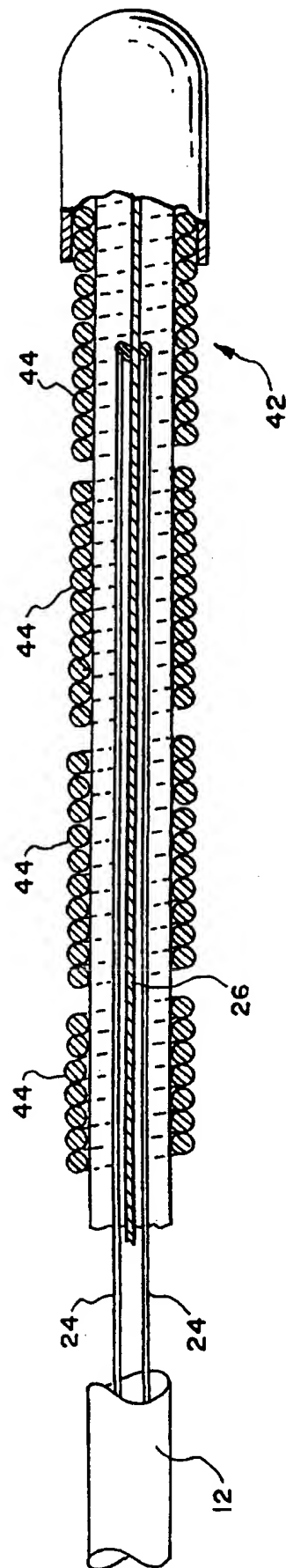


**FIG. 3**

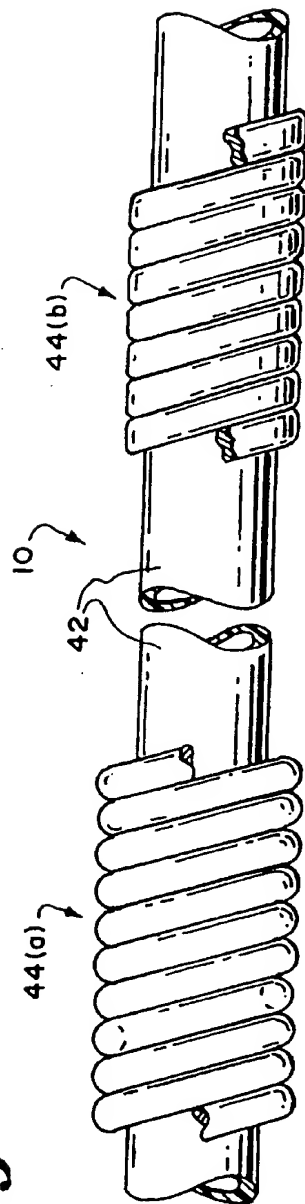


2/11

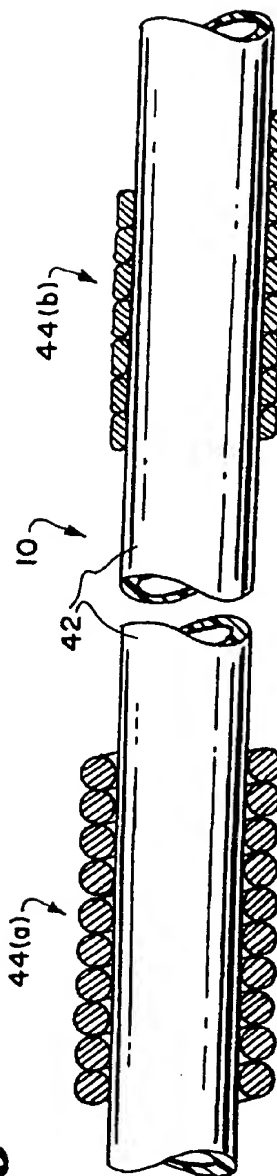
**FIG. 4**



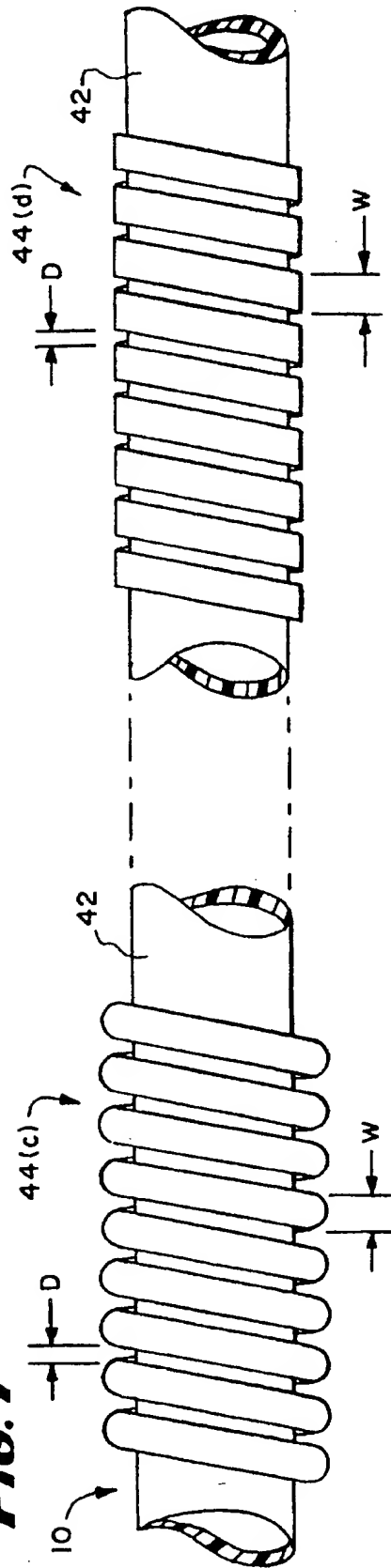
**FIG. 5**



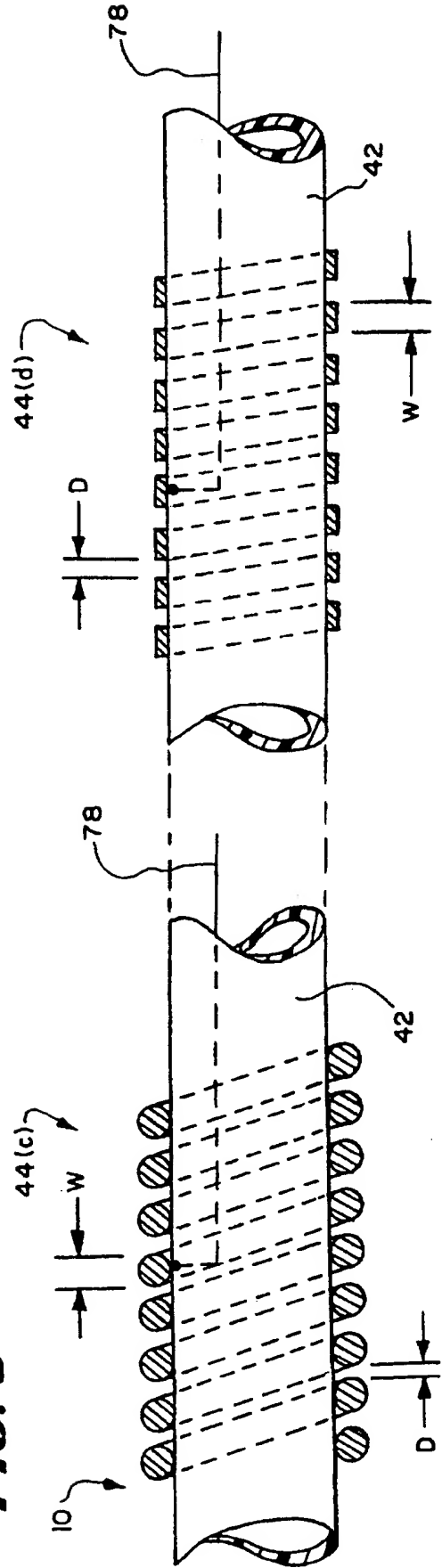
**FIG. 6**



**FIG. 7**

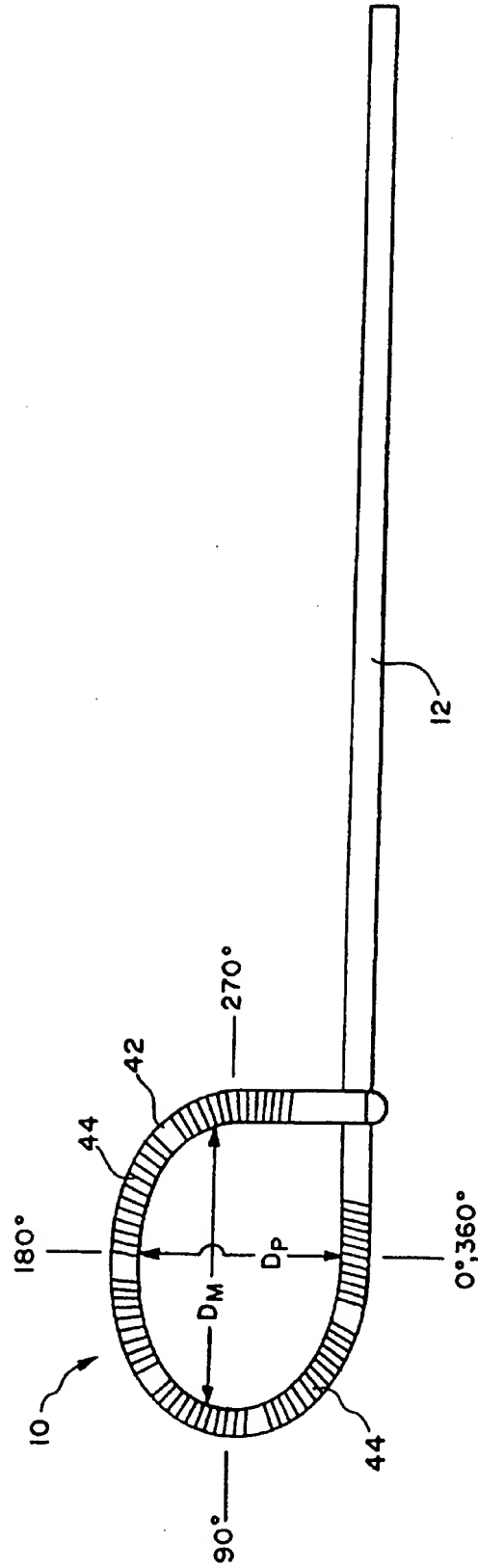


**FIG. 8**



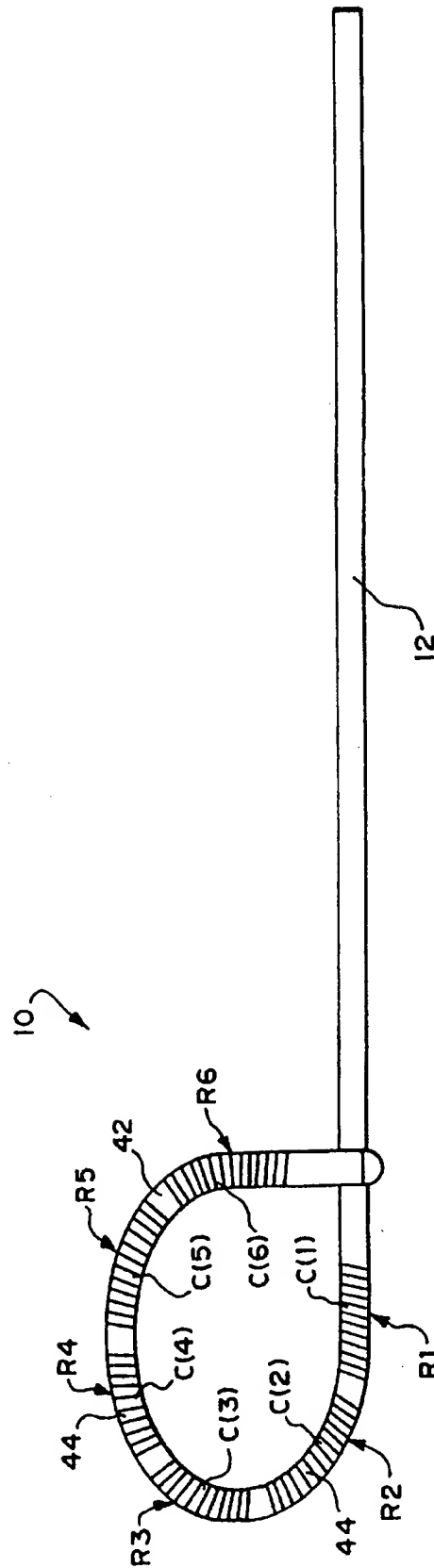
5/11

**FIG. 9**

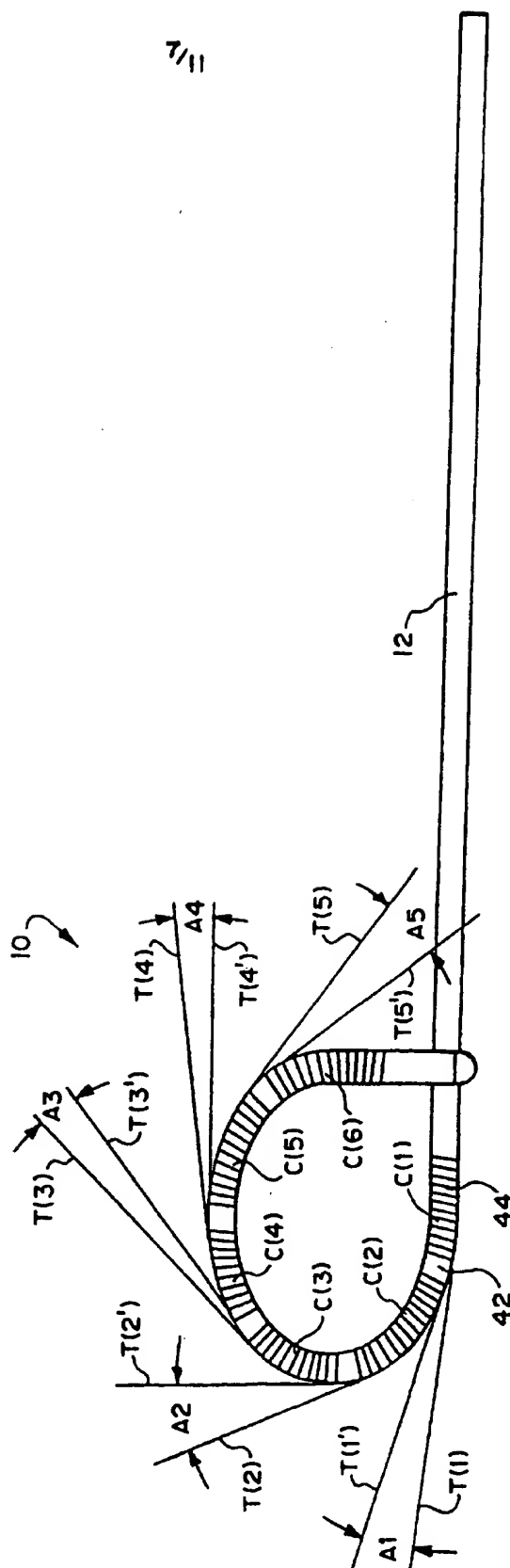


6/11

**FIG. 10**

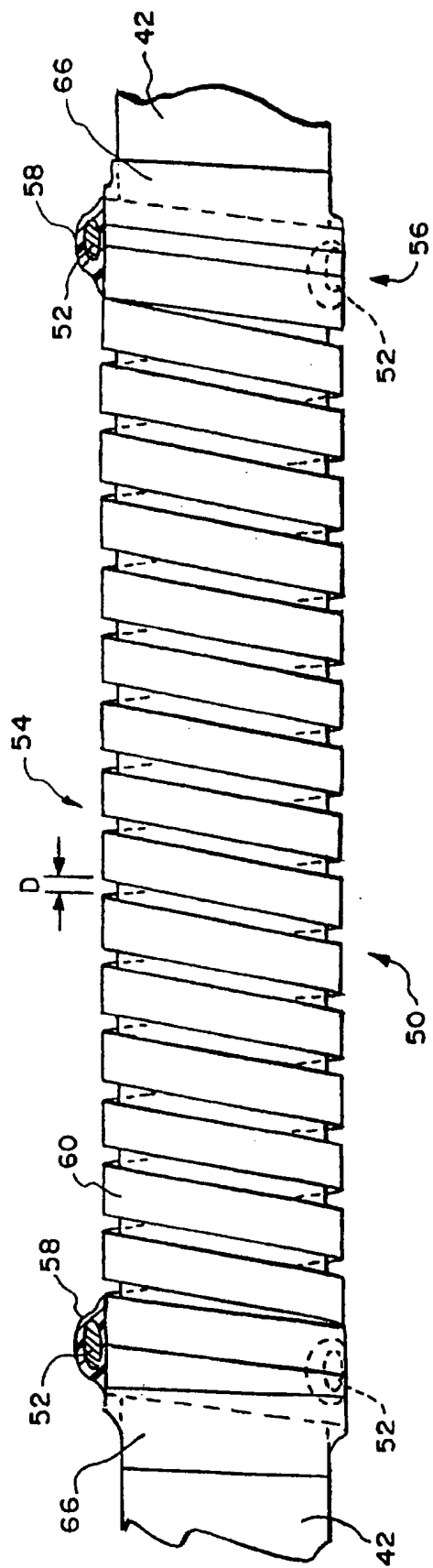


**FIG. 11**

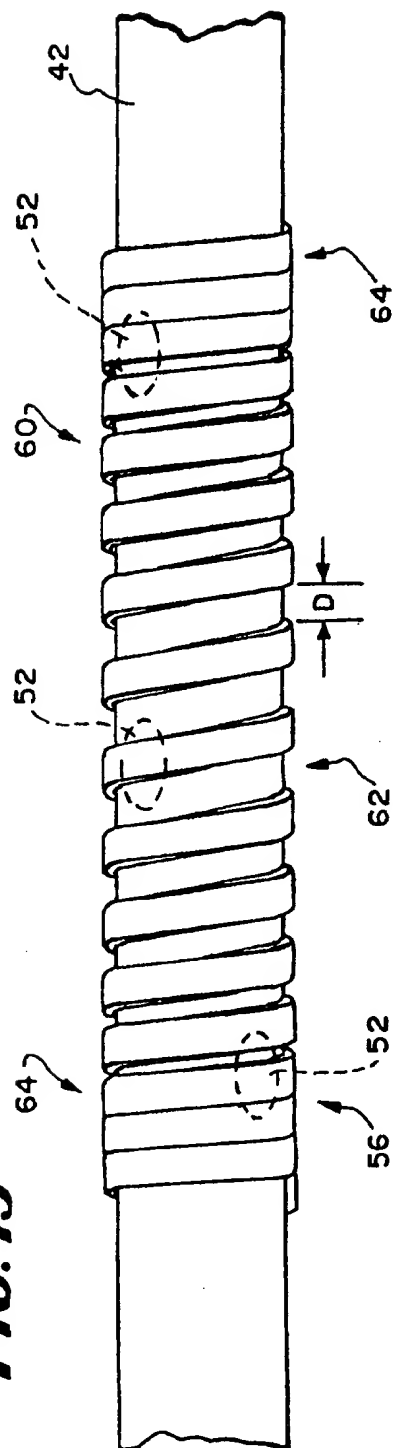


7/11

**FIG. 12**

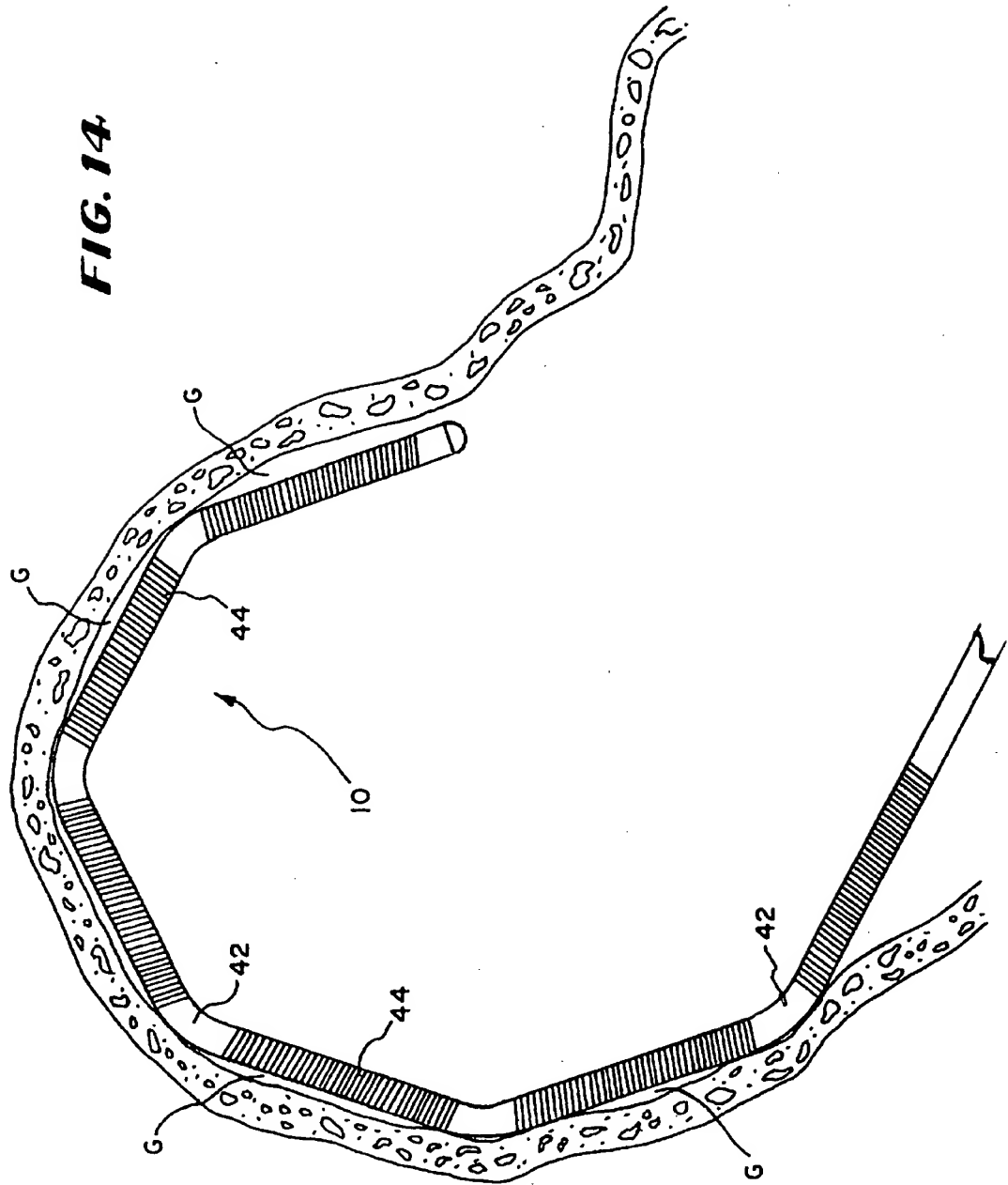


**FIG. 13**

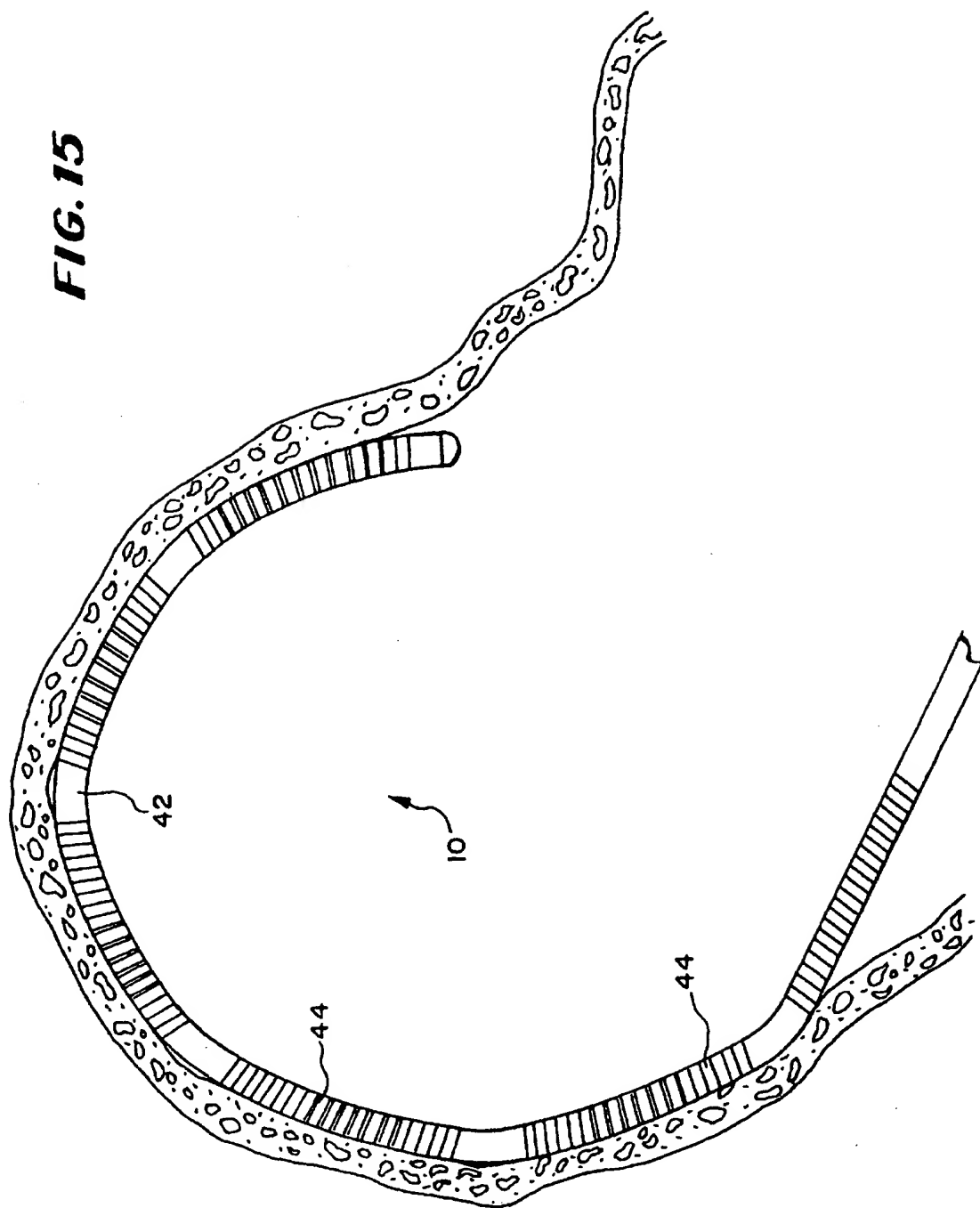


9/11

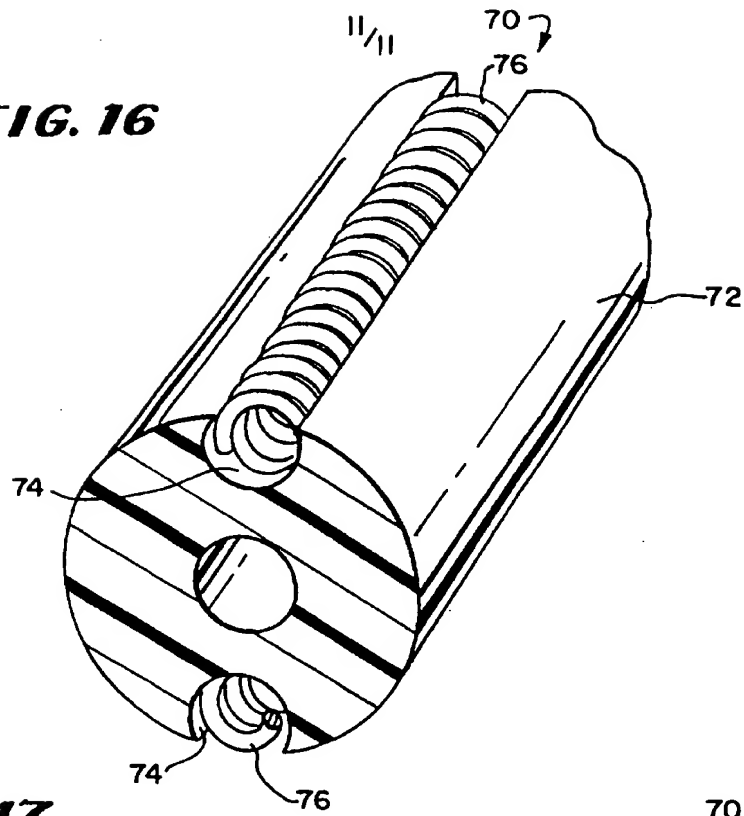
**FIG. 14**



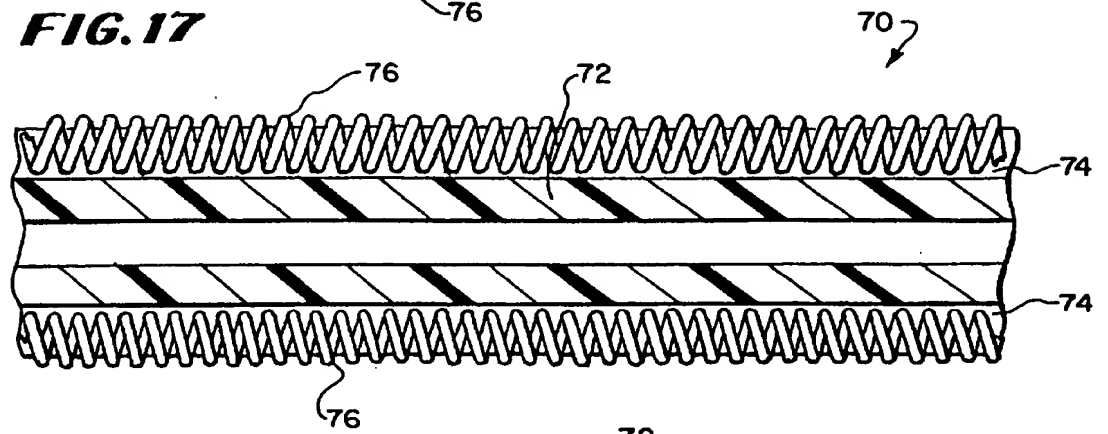
**FIG. 15**



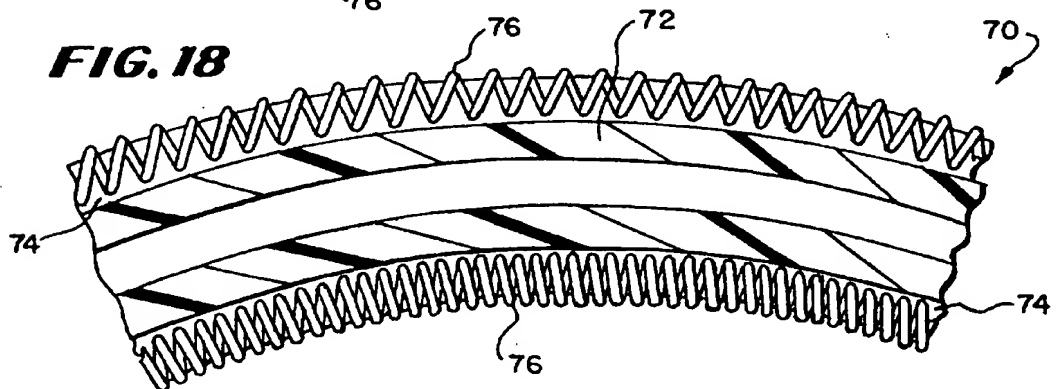
**FIG. 16**



**FIG. 17**



**FIG. 18**



## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/18101

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/36

US CL :606/41

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/642; 606/41, 42, 45-50; 607/100-102, 115, 116, 122

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
NONE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,334,193 A (NARDELLA) 02 August 1994, whole document.	11, 12, 14-17, 23-26, 33-35, 38-40
Y	US 5,254,088 A (LUNDQUIST et al) 19 October 1993, whole document.	11-13, 15-17, 23-26, 33-35, 38-40
Y	US 5,016,808 A (HEIL, JR. et al) 21 May 1991, whole document	14, 23, 33
A	US 4,633,889 A (TALALLA et al) 06 January 1987, figures.	1-40
A	US 4,960,133 A (HEWSON) 02 October 1990, figures.	1-40

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E* earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z* document member of the same patent family
*O* document referring to an oral disclosure, use, exhibition or other means	
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

08 JANUARY 1997

Date of mailing of the international search report

14 FEB 1997

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3590

Authorized officer

MICHAEL PEFFLEY

Telephone No. (703) 308-4305